

PATENT COOPERATION TREATY

PCT



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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference CPS41234	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/CN2004/000458	International filing date (day/month/year) 09.MAY.2004 (09.05.2004)	Priority date (day/month/year) 10.MAY.2003 (10.05.2003)
International Patent Classification (IPC) or national classification and IPC IPC7: C12N15/86, C12N15/12, A61K48/00, A61P17/00		
Applicant PENG, Zhaohui et al.		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>27</u> sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand 14.Sep.2004(14.09.2004)	Date of completion of this report 06.Sep.2005(06.09.2005)	
Name and mailing address of the IPEA/CN The State Intellectual Property Office, the P.R.China, 6 Xitucheng Rd., Jimen Bridge, Haidian District, Beijing, China 100088 Facsimile No. 86-10-62019451	Authorized officer KE,Ke Telephone No. (86-10):62085090	

Form PCT/IPEA/409 (cover sheet) (April 2005)

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement:**

Novelty (N)	Claims 4-8	YES
	Claims 1-3,9	NO
Inventive step (IS)	Claims	YES
	Claims 1-9	NO
Industrial applicability (IA)	Claims 1-9	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

The document as followed is cited by the report:

Document 1(D1):THE JOURNAL OF GENE MEDICINE 2000,2 (6) , 426-432,

Toshiro Shirakawa et al:P53 Adenoviral vector(Ad-CMV-p53) induced prostatic growth inhibition of primary cultures of human prostate and an experimental rat model.

Document 2(D2):CN1401778A 12.03.2003

About novelty:

D1 has disclosed that the recombinant of adenoviral vector and p53 can be used in the treatment of prostatic hyperplasia.Prostatic hyperplasia is a kind of proliferative disease.So the technical solution of claim 1 has been disclosed by D1.Claim 1 don't appear to be novel and don't appear to meet the criteria mentioned in article 33(2)PCT.

Claims 2,3,9 are dependent claims of claim 1.The additional technical features of these claims have been disclosed in D1(such technical features lie in "production of recombinant adenoviruses" and "in vivo experimental design" of "materials and methods" of D1).Thus claims 2,3,9 don't appear to be novel and don't appear to meet the criteria mentioned in article 33(2)PCT.

The technical solutions of claims 4-8 aren't disclosed .Thus,claims 4-8 possess novelty and meet the criteria mentioned in article 33(2)PCT.

About inventiveness:

Claims 4,5 are dependent claims of claim 1.The additional technical features of them are the products defined by the preparation method. Though D1 didn't disclosed the preparation method of the recombinant in detail,D2 disclosed the recombinant which was prepared by the same method as that of claims 4-5(see the claims). There is no substantive difference between the products of D1 and D2.It's easy for the person skilled in the relevant field of technology to realize that such similar products have the same use. So it's obvious for the person skilled in the relevant field of technology to obtain the technical solutions of claims 4-5 through combination of D1 and D2 . Thus,claims 4 and 5 don't appear to be inventive and don't appear to meet the criteria mentioned in article 33(3)PCT.

Claims 6-8 are dependent claims of claim 1.The additional technical features of them are the types of proliferative diseases.Because these proliferative diseases have similar pathogenesis with prostatic hyperplasia,the technical solutions of claims 6-8 are obvious to the person skilled in the relevant field of technology in light of D1.Claims 6-8 don't appear to be inventive and don't appear to meet the criteria mentioned in article 33(3)PCT.

About industrial applicability:

Claims 1-9 can all be used in treatment of diseases and possess industrial applicability.They all meet the criteria mentioned in article 33(4)PCT.

Box No. I Basis of the report

1. With regard to the language, this report is based on:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rules 12.3(a) and 23.1(b))
- ☐ publication of the international application (Rule 12.4(a))
- ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☐ the international application as originally filed/furnished

☒ the description:

pages _____ as originally filed/furnished

pages * 1-12 _____ received by this Authority on 19.Nov.2004

pages * _____ received by this Authority on _____

☒ the claims:

claims _____ as originally filed/furnished

claims * _____ as amended (together with any statement) under Article 19

claims * 1-9 _____ received by this Authority on 19.Nov.2004

claims * _____ received by this Authority on _____

☒ the drawings:

pages _____ as originally filed/furnished

pages * 1-11 _____ received by this Authority on 19.Nov.2004

pages * _____ received by this Authority on _____

- ☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:
- a. type of material
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☒ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☐ filed together with the international application in electronic form
 - ☐ furnished subsequently to this Authority for the purposes of search and/or examination
 - ☒ received by this Authority as an amendment * on 19.Nov.2004
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

**If Item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."*